
ОРГАНІЗАЦІЯ ТА ЕКОНОМІКА ФАРМАЦІЇ

Recommended by Doctor of Pharmacy, professor M.M.Slobodyanyuk

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ANALYSIS OF THE ASSORTMENT OF IMMUNOBIOLOGICAL MEDICAL PRODUCTS USED FOR CHILDREN ROUTINE IMMUNIZATION AT THE UKRAINIAN PHARMACEUTICAL MARKET

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Key words: immunobiological medical products; routine immunization; pharmaceutical market

Marketing analysis of the assortment structure of immunobiological medical products (IMP) used for children routine immunization has been described in the article. It has been found that the given group of products is represented at the Ukrainian pharmaceutical market by 34 trade names, 65% of which belong to foreign producers, 35% are produced by domestic manufacturers. Among the foreign countries-manufacturers of IMP for children routine immunization Belgium takes the leading place, the share of its registered trade names is 29% of this segment. According to the results of the analysis it has been found that manufacturing a number of vaccines mostly from the foreign "in bulk" form is the feature of domestic IMP production. In particular, such production method for vaccines is used by "PHARMA LIFE" company (Lviv), which forms 33% of the domestic vaccine assortment, and "PHARMEX GROUP" company (Boryspil, Kyiv region), and it is 17% of the assortment. Only "PHARMSTANDARD-BIOLIK" company (Kharkiv) provides the production of vaccines from their own raw materials and forms 50% of the domestic vaccine assortment. During the research vaccines were divided by the amount and direction of action of the components, and mono- and multicomponent vaccines were distributed by the countries-manufacturers. It has been found that mono- and multicomponent vaccines are represented at the Ukrainian pharmaceutical market in an equal amount – 17 trade names. Among the countries-manufacturers of monovaccines the leading place belongs to Ukraine (17.6% of the assortment), among the manufacturers of multicomponent vaccines Belgium takes the first place representing 41% of the assortment. The results of the marketing analysis show the dependence of the Ukrainian market of vaccines, especially multicomponent ones, on import and determine the need for further study of the availability level of IMP for children routine immunization.

The use of vaccines for prevention of infectious diseases proves its efficiency for many years, as evidenced by the nearly 3 million children lives, which according to the World Health Organization can be saved thanks to vaccination every year [20]. According to the experts' opinion the use of new immunobiological medical products (IMP), which will be developed over the next 5-15 years, will enable to prevent mortality of 8 million children per year. The application of modern biotechnologies contributes to continuous improvement of the IMP world market. Today the development of innovative vaccines (DNA-vaccines, vector vaccines, plant vaccines, etc.) and new combined vaccines that can create the immunity against even 7-8 infections is rather active. Scientists also pay attention to the issue of finding new methods for vaccine application (intranasal, dermal). Thus, one may state that the vaccination system serves as a decisive factor in preventing of infant mortality, improving the quality and increasing the life expectancy of for groups of the population [5, 9, 10].

The aim of our work was to analyze the assortment structure of IMP registered in Ukraine for children routine immunization with determination of the current trends and problems in this segment of the domestic pharmaceutical market.

Materials and Methods

During the research we used the information from the State Register of medicines of Ukraine as of 08.01.2014 and the reference book "Compendium – Medicines".

Mathematical and graphical methods of analysis were used for the study.

Results and Discussion

According to the Order of the Ministry of Public Health of Ukraine from 16.09.2011 No.595 "About the procedure of prophylactic immunization in Ukraine and control of the quality and turnover of immunobiological medical products" the compulsory children immunization by age is provided against 10 infectious diseases, namely *diphtheria, pertussis, measles, poliomyelitis, tetanus, tuberculosis, rubella, mumps, hepatitis B and Haemophilus influenza b* [6].

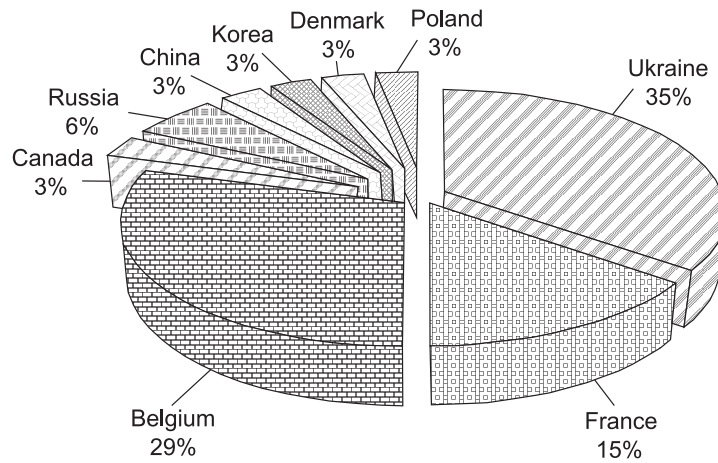


Fig. 1. The ratio of IMP registered in Ukraine for routine immunization of children according to the countries-producers.

According to the ATC classification system the IMP used for routine immunization of children belong to group J – Antimicrobial medications for systemic use and constitute a subgroup of the second level J07 – Vaccines.

Based on data from the State Register of medicines of Ukraine it was found that 34 IMP trade names that could be used for routine vaccination of children were registered in Ukraine on 08.01.2014 [1, 2].

The analysis of the IMP assortment according to the countries-producers has shown that 65% (22 trade names) of the specified segment belong to foreign producers and only 35% (12 trade names) – to domestic ones. Results of the analysis of the assortment structure of foreign IMP suggest that the Belgian vaccines take the leading position at the market, namely 29% (10 trade names). The French manufacturer offers 5 vaccines to the market, and it is 15% of the segment. The market share of IMP consisting of the Russian companies is equal to 6% (2 trade names). The smallest shares, namely 3% of the market each, are occupied by such countries as Canada, China, Korea, Denmark and Poland; they produce 1 vaccine for the domestic market (Fig. 1) [4].

The characteristic feature of domestic production of IMP is that a quite significant share of vaccines is produced mainly from foreign “in bulk” forms. Bulk drugs are pharmaceutical products intended for manufacture of finished products and passed all stages of the production process, except for the final packaging and labeling by another manufacturer. The essence of the production process is that a manufacturing company makes a product and sends it to another company that is engaged in its packaging and labeling.

Therefore, the next stage of our research was sorting of domestic drugs registered in Ukraine according to the manufacturers. Based on the results of the research it has been found that only “Pharmstandard-Biolik” JSC (Kharkiv) provides the production of vaccines from their own raw materials; it has 6 vaccines at the market, and it is 50% of the domestic IMP registered for routine children immunization. These vaccines include diphtheria toxoid (*Dip-M-Biolik*), tetanus toxoid (*TT-Biolik*), tetanus toxoid in combination with diphtheria toxoid (*DT-*

Biolik, *DT-M-Biolik*), acellular combined adsorbed vaccine for prevention of diphtheria, tetanus and pertussis (*DTP-Biolik*) and recombinant liquid vaccine for prevention of hepatitis B. “PHARMA LIFE” company (Lviv) provides 33% of the domestic vaccine assortment and is represented by 4 trade names. In particular, from “in bulk” form of GlaxoSmithKline Biologicals s.a. company (Belgium) this company produces vaccine against hemophilus influenzae b *HIBERYKS*, vaccine against diphtheria, tetanus and pertussis *INFANRIX*, vaccine against measles, mumps and rubella *PRIORIX* and from “in bulk” form of the Institute of Immunology Inc. (Croatia) – vaccine against rubella *KRASLAYF*. “FARMEKS GROUP” company (Boryspil, Kyiv region) produces 2 vaccines (17% of the assortment) – vaccine against poliomyelitis *IMOVAKS POLIO* and vaccine against diphtheria, hemophilus influenzae b, pertussis, poliomyelitis and tetanus *PENTAXIM* (both – from the “in bulk” form of the company Sanofi Pasteur, France) (Fig. 2).

In present-day conditions new vaccines that can simultaneously create protection against several infectious diseases are continuously developed [15, 19]. It should be mentioned that vaccines, which after their introduction create the immunity against several infectious diseases, are called multicomponent (polyvalent) vaccines, and vaccines, which provide the possibility of creating

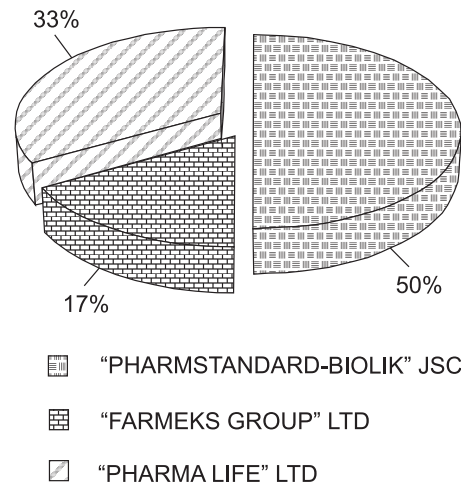


Fig. 2. The ratio of domestic IMP for routine immunization of children according to the manufacturers.

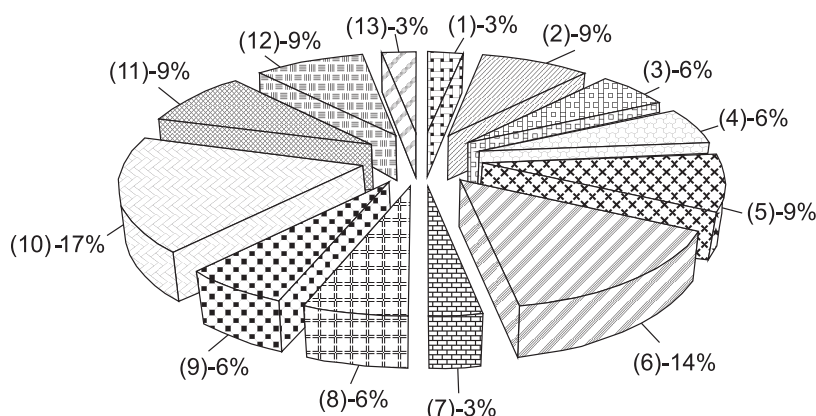


Fig. 3. The ratio of IMP for the routine immunization of children by the amount and direction of action of the components: 1 – Vaccine against diphtheria; 2 – Vaccine against hemophilus influenzae b; 3 – Vaccine against tetanus; 4 – Vaccine against tuberculosis; 5 – Vaccine against hepatitis B; 6 – Vaccine against poliomyelitis; 7 – Vaccine against rubella; 8 – Vaccine against diphtheria and tetanus; 9 – Vaccine against measles, mumps and rubella; 10 – Vaccine against pertussis, diphtheria and tetanus; 11 – Vaccine against diphtheria, pertussis, poliomyelitis and tetanus; 12 – Vaccine against diphtheria, hemophilus influenzae b, pertussis, poliomyelitis and tetanus; 13 – Vaccine against diphtheria, hemophilus influenzae b, pertussis, poliomyelitis, tetanus and hepatitis B.

the immunity against only one infection, are called monocomponent. The advantages of the multicomponent vaccines are [8]:

- decrease in the content of adjuvants, preservatives and stabilizers while using a combined vaccine comparing to application of several monovaccines; it reduces the risk of immunization reactions and complications [13];
- cost savings (the cost of one vaccine in the composition of a combined vaccine is less than the cost of a monovaccine);
- reduction of the number of visits to a doctor, saving of the parents' time;
- decrease of the emotional stress of the child;
- more timely and complete fulfillment of the prophylactic immunization chart [17];
- reduction of the number of injections during the vaccination according to the National vaccination calendar. Thus, the use of combined vaccines allows to immunize a child in the first 18 months of life with 9-11 vaccinations while using monovaccines involves 14-17 vaccinations [7, 12, 18].

In view of the abovementioned, the next step of our study was the classification of vaccines used for routine immunization of children according to the amount and direction of action of the components. Based on the results of the research it has been found that the combined vaccine against *diphtheria, tetanus and pertussis* (DTP), which is represented by 6 trade names, takes the largest share at the market (Fig. 3). The vaccine mentioned is one of the first polyvalent vaccines created and used in Ukraine in the course of preventive vaccination over 60 years. Other combined vaccines that include these three components were created exactly on the basis of DTP-vaccine. Somewhat smaller share in the market, namely 14% (5 trade names), is taken by vaccine against *polio*. Monovaccines against *hemophilus influenzae b* and *hepatitis B*, as well as combined vaccines against *diphtheria, pertussis, polio and tetanus* and against *diphtheria, hemophilus influenzae b, pertussis, polio and tetanus* occupy 9% of the studied assortment, and it is 3

trade names each. The vaccine against *tuberculosis* and the vaccine against *tetanus* are 6% (2 trade names) of the segment analyzed. The similar situation is observed with polyvalent vaccines against *diphtheria and tetanus* and against *measles, mumps and rubella*. Monovalent vaccines against *diphtheria* and against *rubella* and a six-component vaccine against *diphtheria, hemophilus influenzae b, pertussis, polio, tetanus and hepatitis B* take 3% of the segment of the market under research represented only by 1 trade name each [3].

The production of **multicomponent vaccines** indicates a considerable state interest in organizing and conducting vaccination, as well as its willingness to spend significant resources in this healthcare branch due to the fact that the production of vaccines is much less lucrative than, for example, of antibiotics [11, 14, 16]. Therefore, the next stage of our study was the structural analysis of countries-manufacturers of monovaccines and multicomponent vaccines registered in Ukraine, the results of which are given in Table, Fig. 4 and 5.

According to the research results **monovaccines** and **combined vaccines** are represented at the domestic pharmaceutical market in equal amounts – 17 trade names. Among the countries-manufacturers of monovaccines the leading place belongs to Ukraine, which produces 6 trade names (17.6% of the assortment) for the market, however, 3 of these 6 vaccines are made not of the own raw material, but from “in bulk” forms of foreign manufacturers. Shares that make up 8.8% are occupied by manufacturers from France and Belgium. Vaccines produced in Russia are 5.9% of the assortment analyzed, and the least amount of the vaccines registered in Ukraine (2.9% of the assortment) belong to Denmark, Poland and Korea.

Two-component vaccines are produced for the market only by the Ukrainian manufacturers and are up to 5.9% of the IMP registered for the routine immunization of children.

Among the countries-manufacturers of **three-component vaccines** by the number of the registered IMP the leading places belong to Belgium and Ukraine, each of them offer 3 vaccines of the given composition (8.8%,

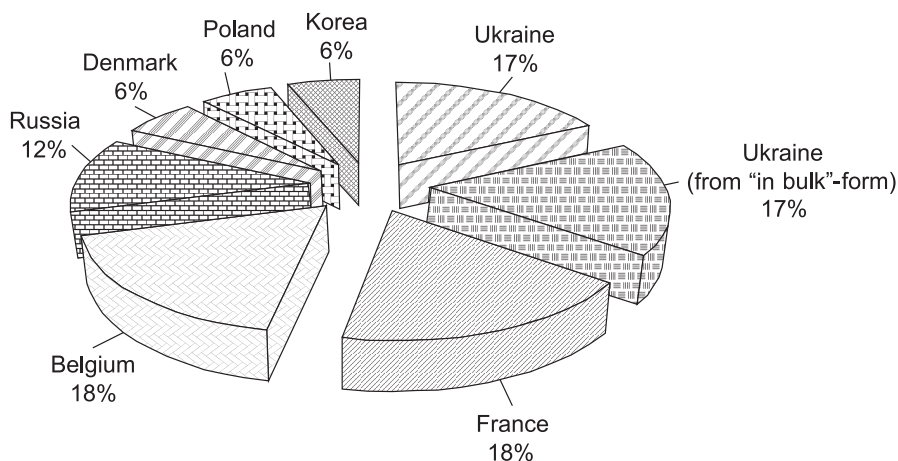


Fig. 4. The structure of countries-manufacturers of *monovaccines* according to the State Register of medicines of Ukraine.

Table

The ratio of monovaccines and multicomponent vaccines registered in Ukraine according to countries-manufacturers

Country-manufacturer	The number of the trade names registered	The share, %
1	2	3
Monovaccines		
Ukraine	3	8.8
Ukraine (from foreign "in bulk" form)	3	8.8
France	3	8.8
Belgium	3	8.8
Russia	2	5.9
Denmark	1	2.9
Poland	1	2.9
Korea	1	2.9
In all:	17	50
Two-component vaccines		
Ukraine	2	5.9
Three-component vaccines		
Canada	1	2.9

Table continued

1	2	3
Belgium	3	8.8
China	1	2.9
Ukraine (from foreign "in bulk" form)	2	5.9
Ukraine	1	2.9
In all:	8	23.5
Four-component vaccines		
Belgium	2	5.9
France	1	2.9
In all:	3	8.8
Five-component vaccines		
Belgium	1	2.9
France	1	2.9
Ukraine (from foreign "in bulk" form)	1	2.9
In all:	3	8.8
Six-component vaccine		
Belgium	1	2.9
The total number:	34	100

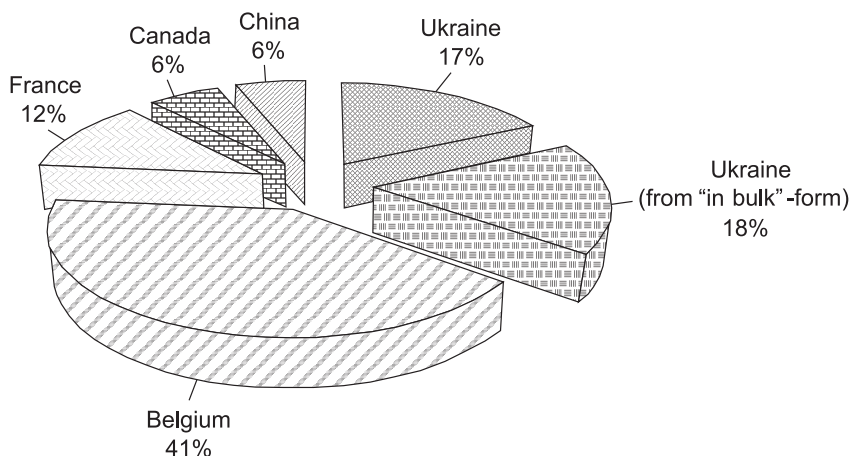


Fig. 5. The structure of countries-manufacturers of *multicomponent vaccines* according to the State Register of medicines of Ukraine.

respectively). However, 2 of 3 of the Ukrainian registered vaccines are produced from foreign “in bulk” form and only one – from the own raw material.

Four-component vaccines are offered to the market only by foreign manufacturers, 2 of them belong to the Belgian manufacturer and 1 – to the French manufacturer, it is 5.9% and 2.9%, respectively.

Countries-manufacturers of **five-component vaccines** occupy a share of 8.8% of the current assortment uniformly distributed between France, Belgium and Ukraine, each of them offer 1 vaccine to the market. It should be noted that the Ukrainian companies manufacture vaccines from foreign “in bulk” forms.

Only Belgium produces a **six-component vaccine** to the Ukrainian pharmaceutical market, its share is equal to 2.9% of the assortment.

Thus, according to the results of the studies there is a clear tendency of dependence of the IMP domestic market on the import of both manufactured vaccines and the raw material for their manufacture by domestic companies.

CONCLUSIONS

1. It has been found that in the assortment of IMP for the routine immunization of children the foreign vaccines are dominated, their share is 65% (22 trade names). Domestic manufacturers offer 35% of the assortment at the market (12 trade names).

2. Among domestic manufacturers by the number of the vaccines registered in Ukraine “Pharmstandard-Biolik” JSC (Kharkiv) takes the leading place, it produces 6 vaccines for the market, and it is 50% of the domestic registered IMP for routine immunization of children.

3. Monovaccines and multicomponent vaccines are represented in an equal amount at the pharmaceutical market. The leader in production of monovaccines is Ukraine, of multicomponent vaccines – Belgium.

Taking into account a rather difficult situation for the population attitude towards vaccination in Ukraine our future research will be aimed at determining the availability of information about IMP for routine immunization of children.

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АНАЛІЗ АСОРТИМЕНТУ МЕДИЧНИХ ІМУНОБІОЛОГІЧНИХ ПРЕПАРАТІВ, ЩО ВИКОРИСТОВУЮТЬСЯ ДЛЯ ПЛАНОВОЇ ВАКЦИНОПРОФІЛАКТИКИ ДІТЕЙ НА ФАРМАЦЕВТИЧНОМУ РИНКУ УКРАЇНИ

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Ключові слова: медичні імунобіологічні препарати; планова вакцинопрофілактика; фармацевтичний ринок

Проведено маркетинговий аналіз асортиментної структури медичних імунобіологічних препаратів (МІБП), які використовуються для планової вакцинопрофілактики дітей. Встановлено, що зазначена група препаратів представлена на українському фармацевтичному ринку 34 торговими назвами, з яких 65% належать іноземним виробникам, а 35% виробляються вітчизняними виробниками. Серед іноземних країн-виробників МІБП для планової вакцинопрофілактики дітей лідируюче місце посідає Бельгія, частка зареєстрованих торгових назв якої становить 29% від зазначеного сегменту. За результатами досліджень встановлено, що характерною особливістю вітчизняного виробництва МІБП є виготовлення низки вакцин переважно з форми *in bulk* іноземного виробництва. Зокрема такий спосіб виробництва вакцин використовується компаніями ТОВ «ФАРМА ЛАЙФ» (м. Львів), якою формується 33% асортименту вітчизняних вакцин, та ТОВ «ФАРМЕКС ГРУП» (м. Бориспіль, Київська обл.), що складає 17% асортименту. Виготовлення вакцин з власної сировини здійснює лише ПАТ «ФАРМСТАНДАРТ-БІОЛІК» (м. Харків), що формує 50% асортименту вітчизняних вакцин. У ході досліджень проведено розподіл вакцин за кількістю та напрямом дії компонентів, а також розподіл моно- та багатокомпонентних вакцин за країнами-виробниками. Встановлено, що моно- та багатокомпонентні вакцини представлені на вітчизняному фармацевтичному ринку в рівній кількості – по 17 торгових назв. Серед країн-виробників моновакцин лідируюче місце належить Україні (17,6% асортименту), серед виробників багатокомпонентних вакцин перше місце посідає Бельгія, що складає 41% асортименту. Результати проведеного маркетингового аналізу свідчать про залежність українського ринку вакцин, особливо багатокомпонентних, від імпорту, що зумовлює необхідність подальшого вивчення рівня забезпеченості населення МІБП для планової вакцинопрофілактики дітей.

АНАЛИЗ АССОРТИМЕНТА МЕДИЦИНСКИХ ИММУНОБИОЛОГИЧЕСКИХ ПРЕПАРАТОВ, КОТОРЫЕ ИСПОЛЬЗУЮТСЯ ДЛЯ ПЛАНОВОЙ ВАКЦИНОПРОФИЛАКТИКИ ДЕТЕЙ НА ФАРМАЦЕВТИЧЕСКОМ РЫНКЕ УКРАИНЫ

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Ключевые слова: медицинские иммунобиологические препараты; плановая вакцинопрофилактика; фармацевтический рынок

Проведен маркетинговый анализ асортиментной структуры медицинских иммунобиологических препаратов (МИБП), используемых для плановой вакцинопрофилактики детей. Установлено, что указанная группа препаратов представлена на украинском фармацевтическом рынке 34 торговыми названиями, из которых 65% принадлежат иностранным производителям, а 35% производятся отечественными производителями. Среди иностранных стран-производителей МИБП для плановой вакцинопрофилактики детей лидирующее место занимает Бельгия, часть зарегистрированных торговых названий которой составляет 29% от указанного сегмента. По результатам исследований установлено, что характерной особенностью отечественного производства МИБП является изготовление ряда вакцин преимущественно из формы *in bulk* иностранного производства. В частности такой способ производства вакцин используется компаниями ООО «ФАРМА ЛАЙФ» (г. Львов), которые формируют 33% ассортимента отечественных вакцин, и ООО «ФАРМЕКС ГРУПП» (г. Борисполь, Киевская обл.), что составляет 17% ассортимента. Изготовление вакцин из собственного сырья осуществляет только ОАО «ФАРМСТАНДАРТ-БИОЛЕК» (г. Харьков), который формирует 50% ассортимента отечественных вакцин. В ходе исследований проведено распределение вакцин по количеству и направлению действия компонентов, а также распределение моно- и многокомпонентных вакцин по странам-производителям. Установлено, что моно- и многокомпонентные вакцины представлены на отечественном фармацевтическом рынке в равном количестве – по 17 торговых названий. Среди стран-производителей моновакцин лидирующее место принадлежит Украине (17,6% ассортимента), среди производителей многокомпонентных вакцин первое место занимает Бельгия, что составляет 41% ассортимента. Результаты проведенного маркетингового анализа свидетельствуют о зависимости украинского рынка вакцин, особенно многокомпонентных, от импорта, что обуславливает необходимость дальнейшего изучения уровня обеспеченности населения МИБП для плановой вакцинопрофилактики детей.